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Registration Decision RD2013-26

Pyrimethanil

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Registration Decision for Pyrimethanil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Pyrimethanil Technical Fungicide and Ecofog-160, containing the technical grade active ingredient pyrimethanil, for postharvest treatment of apples and pears by thermal fogging to control gray mould and suppress blue mould.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-10, *Pyrimethanil*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for pyrimethanil and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-10. This decision is consistent with the proposed registration decision stated in PRD2013-10.

For more details on the information presented in this Registration Decision, please refer to PRD2013-10, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Pyrimethanil?

Pyrimethanil is the active ingredient present in Ecofog-160. It is a member of the anilinopyrimidine family of fungicides and belongs among the Fungicide Resistance Action Committee's Group 9 fungicides. Pyrimethanil acts by preventing secretion of the fungal enzymes necessary for the pathogen infection process.

Health Considerations

Can Approved Uses of Pyrimethanil Affect Human Health?

Products containing pyrimethanil are unlikely to affect your health when used according to label directions.

Potential exposure to pyrimethanil may occur through the diet (food and water) or when handling and applying the product or when entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

A detailed assessment of the toxicology database for technical grade pyrimethanil can be found in the REG2006-04, *Pyrimethanil*. Ecofog-160 is a new end-use product for a new use of pyrimethanil, and additional toxicology data and information were provided with the current application. Waiver requests for the short-term inhalation toxicity and short-term dermal toxicity data requirements, as well as an acute toxicity package for Ecofog-160, were submitted. A new mouse oncogenicity study and a rat immunotoxicity toxicity study were also submitted.

In laboratory animals, the acute toxicity of the end-use product Ecofog-160 (containing pyrimethanil) was low via the oral, dermal and inhalation routes. It was moderately irritating to the eyes and minimally irritating to the skin, and caused an allergic skin reaction. Consequently, the hazard signal words "WARNING EYE IRRITANT" and "POTENTIAL SKIN SENSITIZER" are required on the product label.

Health effects in animals given repeated doses of the active ingredient pyrimethanil included effects on the thyroid and liver. There was no evidence that pyrimethanil damaged genetic material but it did, however, cause thyroid tumours in rats. Pyrimethanil did not cause birth defects in animals and did not affect the ability to reproduce. When pyrimethanil was given to pregnant or nursing animals, effects on the developing fetus (decreased body weights, increased runts) and juvenile animal (decreased body weight gains) were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to pyrimethanil than the adult animal. Pyrimethanil caused functional effects, possibly related to the nervous system, at high doses in rats after a single dose.

The risk assessment protects against the effects of pyrimethanil by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and all infants less than 1 year old, the subpopulation which would ingest the most pyrimethanil relative to body weight, are expected to be exposed to less than 21% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from pyrimethanil is not of concern for all population subgroups.

Acute dietary (food and water) estimates for the general population and all population subgroups were less than 22% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was all infants less than 1 year old.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

The residue data submitted to support the registration of pyrimethanil as a postharvest application by thermal fogging on pome fruits are adequate. For the MRLs for this active ingredient on pome fruits, please refer to EMRL2010-26.

Occupational Risks From Handling Ecofog-160

Occupational risks are not of concern when Ecofog-160 is used according to the proposed label directions, which include protective measures.

Workers who mix, load or apply Ecofog-160 can come in dermal contact with pyrimethanil residues on the skin and can be exposed to pyrimethanil by inhalation. Therefore, the label specifies that mixer/loaders and fogging applicators must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes, socks and protective eyewear. Fogging applicators must also wear a full-face respirator or self-contained breathing apparatus to protect from blow-back of the superheated fog and exposure to pyrimethanil, in case of system failure of the application equipment. The label also requires that workers who enter treated storage rooms must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes, socks, and full-face self-contained breathing apparatus gear. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for workers, the risks to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible, provided that a specific venting and filtration system that yields 100% filter efficiency is put in place during and after application.

Environmental Considerations

What Happens When Pyrimethanil Is Introduced Into the Environment?

When pyrimethanil is applied as the fungicide Ecofog-160 to pome fruits by thermal fogging in closed storage facilities, minimum exposure of exterior soil and water is expected. Pyrimethanil has a low potential for volatilization and, therefore, is not expected to remain in the atmosphere for extended periods and is not expected to result in long range atmospheric transport.

Value Considerations

What Is the Value of Ecofog-160?

Ecofog-160 is a fungicide for postharvest treatment of apples and pears through thermal fogging. Ecofog-160 is a preventative treatment effective in the control of gray mould and the suppression of blue mould, which are the two principal postharvest diseases of pome fruit.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Ecofog-160 to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with pyrimethanil on the skin or through inhalation of spray mists, anyone mixing, loading and applying Ecofog-160 must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes, socks and protective eyewear. Fogging applicators must also wear a full-face respirator or self-contained breathing apparatus to protect from blow-back of the superheated fog and exposure to pyrimethanil, in case of system failure of the application equipment. In addition, since bystanders may be exposed to vented air from the storage rooms, a specific venting and filtration system that yields 100% filter efficiency must be in place during and after application.

Environment

For the proposed use on stored pome fruits in closed treatment facility, environmental exposure to pyrimethanil residues is expected to be minimal and, thus, no risk mitigation measures are required.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-10, *Pyrimethanil)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.